REMARKS

The applicants appreciate the examiner's review of the application, and request reconsideration of the pending claims.

35 U.S.C. § 112

Claims 1-19 were rejected under 35 U.S.C. § 112, first paragraph. The Office Action asserts that "[t]he specification does not provide any description of the 'deformable stem' and the 'plug member' …." However, the deformable stem and the plug member are supported by the specification.

For example, although the specification does not use the specific term "stem," the specification nevertheless describes a deformable stem located in the valve body and shiftable therein. See gland 12 shown throughout the figures and discussed at page 7, lines 5-13. The specification also describes this stem as having an aperture. See aperture 42 shown in figure 1 and discussed at page 4, lines 21-22. The specification also describes this aperture as being configured such that, when an external instrument is engaged with the aperture, the stem shifts within said valve body and the aperture deforms to allow liquid to flow therethrough to or from the external instrument. See figures 3-6, page 7, lines 14-25, and page 4, line 27 to page 5, line 3. It is not seen how the term "stem" could be appropriate for the deformable structure of Patent No. 6,036,171 to Weinheimer but, at the same time, be inappropriate for the deformable structure of the present application.

In addition, although the specification does not use the specific term "plug member," the specification nevertheless describes a plug member in the stem. See rigid cannula 14, which cooperates with the deformable gland 12 to plug the interior of the valve via seal 22, as shown in figures 1-6, and described in page 4, lines 15-16. The specification also describes this plug member as being shiftable to a position of generally sealed engagement with the stem while the instrument is still engaged with the aperture in the stem. See the seal area 22 shown in figure 2, and discussed at page 6, line 28 to page 7, line 4 and page 7, lines 7-9. At page 5, lines 13-14, the application notes that "[t]he outlet end 58 of the cannula 14 is shaped so as to provide a seal against the gland 12." In other words, the rigid cannula described in the present specification is shaped so as to provide a plug—*i.e.*, a seal—against the gland. Thus, the shiftable rigid member of the present application is no less a "plug" than the shiftable rigid member of the Weinheimer patent.

35 U.S.C. § 103

The present invention is directed to a valve that includes both a deformable stem with an aperture that deforms to allow liquid to flow through the valve and a plug member that is shiftable to a position that provides a seal (*i.e.*, a plug) against the stem. This combination of elements provides the valve with a double seal arrangement: one seal (which is opened when the stem's aperture is deformed by an external instrument) can keep contaminants from entering the valve while the valve is closed, and the other seal (which is opened by shifting the plug member in the stem) can provide a plug

against high back pressure emanating from the valve's outlet. This claimed structure could not have been obvious in light of the prior art.

The Office Action relies on Patent No. 6,079,432 to Paradis in light of Patent No. 5,620,434 to Brony to assert the claimed invention would have been obvious. However, these references do not disclose structures that could be adapted to arrive at the present invention.

The Paradis patent does not use the term "stem." It does use the term "plug," but uses the term "plug" to describe the deformable member, item 20. The rigid internal cannula 14 shown in Paradis is not shiftable and cannot act like a plug. To the contrary, Paradis's cannula 14 is intended to act as a wedge to open the deformable "plug 20" and thereby allow fluid to pass therethrough; Paradis's cannula is not intended to act—and cannot act—as a plug that presses against the deformable member 20 to stop flow through the valve even in the presence of back pressure. The intended function of Paradis's cannula—namely, wedging open deformable "plug 20"—is antithetical to the function of the plug member of the present invention, which is to act as plug sealing against the deformable stem. Thus, Paradis's cannula acts in a manner directly opposite to the plug member of the present invention.

Furthermore, Paradis's internal cannula 14 is intended to remain stationary, so that—as the deformable "plug 20" is pushed down over the stationary cannula—the cannula forces the deformable "plug 20" open. If the Paradis valve were adapted to make the cannula 14 shiftable, the cannula would be unable to perform the function for which it was designed, which is to wedge open the deformable "plug 20." In particular,

if the Paradis cannula were made shiftable, the rigid cannula would simply move with the deformable "plug 20" instead of wedging it open. Again, such an adaptation of Paradis's cannula would be contrary to its intended purpose. Moreover, even if Paradis's cannula were broken off from the exterior rigid housing of the Paradis valve, Paradis's cannula could not function as a plug and would be unable to resist any back pressure.

Given that the modification of the Paradis's valve suggested in the Office Action is unworkable and contrary to Paradis's intent, the Brony patent cannot be seen as suggesting any such modifications to Paradis's valve. In addition, Brony lacks several elements of the claims. The Brony patent does not use the term "stem." Furthermore, the structure of the Brony valve is such that a deformable stem simply cannot be inserted into the Brony valve. Brony also does not show or describe a deformable aperture. Brony does use the term "plug," but uses it for a very different structure from that of the present invention; Brony uses the term "plug" to described protusions (items 42 and 62 in figures 2 and 5) on the caps to the valves. Thus, these "plugs" are not even part of the Brony valve proper.

Thus, the Paradis and Brony references cannot be properly combined in any manner to arrive at the present invention.

Support for New Claims 20-24

The foregoing amendment adds new claims 20-24. Claim 20 is similar to original claim 1. Instead of "a deformable stem" as referred to in claim 1, claim 20 refers to "a flexible, resilient member." See flexible gland 2 in the figures, page 2, lines 9-16, and

page 7, lines 5-13 of the application. Also, instead of "a plug member" as referred to in claim 1, claim 20 refers to "a rigid member." See rigid cannula 14 in the figures, page 2, lines 7-9, and page 6, line 24, to page 7, line 11. The prior art does not teach or suggest a shiftable, rigid member in an apertured, shiftable, flexible, resilient member as claimed in claim 20, such that the rigid member is shiftable to a position of generally sealed engagement with the flexible, resilient member. Thus, the prior art cannot teach or suggest the invention claimed in these new claims.

Filed herewith is a supplemental information disclosure statement citing additional papers from the prosecution of related application no. 10/700,344 of Cote and Ganem.

The application thus is in condition for allowance and such action is earnestly solicited. Applicants request that the Examiner contact the undersigned, Timothy Murphy (617-443-9292), if it will assist examination of the pending claims. If additional fees are required, please charge deposit account number 19-4972.

Respectfully submitted,

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